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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/555,473	05/31/00	BOTTAZZI	2801-18

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HM12/0326

EXAMINER

DHRUVA, B

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/555,473

Applicant(s)

BOTTAZZI ET AL.

Examiner

Bharati R. Dhruva

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-5 and 9-11 are, drawn to a composition comprising a protein, classified in class 530 subclass 350
- II. Claim 6 is drawn to method of ex-vivo treatment of tumor conditions comprising transfecting cells with an expression vector and administering the cells to a tumor patient, classified in class 424 subclass 93.21.
- III. Claim 7-8 and 12, drawn to *in vivo* methods of treating a tumor with a viral vector encoding long pentraxin PTX3, classified in class 514 subclass 44.
- IV. Claims 9-11 drawn to methods of treating tumor comprising administering the protein of the long pentraxin PTX3, classified in class 514 subclass 2.
- V. Claims 9-11 drawn to methods of treating inflammatory disease comprising administering the protein of the long pentraxin PTX3, classified in class 514 subclass 2.
- VI. Claims 9-11 drawn to methods of treating infectious disease comprising administering the protein of the long pentraxin PTX3, classified in class 514 subclass 2.
- VII. Claim 12 is drawn to a method of treating inflammatory disease comprising administering *in vivo* cDNA of long pentraxin PTX3. Classified in class 514 subclass 44.

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VIII. Claim 12 is drawn to a method of treating infectious disease comprising administering *in vivo* cDNA of long pentraxin PTX3. Classified in class 514 subclass 44.

If applicants elect **Group VI or Group VIII** they are further required to select a species from the following groups;

A. Bacteria, Fungi and Protozoa

B. Virus

NOTE : Claims 9-12 are drawn to non-statutory subject matter under 35 USC 101. In the interest of compact prosecution, the claims have been viewed as process claims lacking functional steps for restriction purposes. Applicants should amend the claims appropriately upon restriction.

Inventions of Groups I, IV, V and VI are unrelated to inventions of Groups II, III, VI and VIII. They are different products and they differ with respect to their structures and properties. In the instant case the protein of Groups I, IV, V and VI is a distinct from the DNA construct of Groups II, III, VII and VIII. The DNA construct can be used for the production of protein or transformation of a cell. The protein can be used as an antigen for antibody production or in a diagnostic assay.

Inventions of Groups I, IV, V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

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shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the protein of group I can be used in materially different process such as in any one of the methods of invention of IV, V or VI or in the production of antibodies specific for the protein. Hence the Group I inventions are distinct from Group IV, V and VI.

Inventions of Group IV, Group V and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different methods. Group IV is a method of treating tumor, Group V is method of treating inflammatory disease and Group VI is a method of treating infectious disease. They differ with respect to ingredients, method steps and endpoints: therefore each method is patentably distinct.

Inventions of Groups II, III and Group VI and Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different methods. Groups II and III are methods of treating tumor; Group VI is a method of treating inflammatory disease and Group VIII a method of treating infectious

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disease. They differ with respect to ingredients, method steps and endpoints: therefore each method is patentably distinct.

Inventions Groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different methods. Group II is a method of *ex-vivo* treatment of tumor conditions, and group III is *in vivo* treatment of tumor conditions. They differ with respect to ingredients, method steps and endpoints: therefore each method is patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to non-elected invention the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors are is no longer an inventor of at least one claim remaining in the application. Any amendment to inventorship must accompany by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication from the examiner should be directed to Bharati R. Dhruva whose telephone number is (703)-605-1157. The examiner can normally be reached on M-F (8:30-5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda can be reached on (703)-305-6608. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014 for regular communications and After Final communications.

Questions of formal matters can be directed to the patent analyst Patsy Zimmerman, whose phone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0196.

brd

March 1st, 2001

Karen M. Hauda
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